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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,730	06/20/2006	Akinori Matsukuma	0599-0216PUS1	8642

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EXAMINER

DI CICCO, JOHN R

ART UNIT	PAPER NUMBER
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3739

NOTIFICATION DATE	DELIVERY MODE
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06/27/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/583,730	Applicant(s) MATSUKUMA ET AL.	
	Examiner John R. Di Cicco	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/20/06, 4/20/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5, 9, 15, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Lennox et al. (5,571,088).

Regarding claim 5, Lennox et al. disclose a balloon catheter (abstract) comprising a catheter shaft (10), a balloon (22) attached to the catheter shaft, a first electrode (42) and a second electrode (44) positioned in the balloon with a clearance kept between them along the catheter shaft (Fig. 4 shows space between electrodes), high-frequency power supply leads (49) for supplying high-frequency power to the first and second electrodes (col. 4, lines 48-59; and Fig. 3), and a liquid supply passage (26) for supplying a liquid into the balloon (col. 4, lines 39-47), wherein potential detecting electrodes (18 and 20) for detecting the potentials of the therapeutic site are disposed on the catheter shaft outside the balloon on the front end side or rear end side of the catheter shaft, and potential information deriving leads (49) for deriving the potential information detected by the potential detecting electrodes are provided (col. 4, lines 31-39; and Fig. 3).

Regarding claims 9 and 15, Lennox et al. disclose a balloon catheter, according to claim 5, which further comprises a temperature sensor (50) disposed inside or on the

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outer surface of the balloon (Fig. 3), and temperature information deriving leads for deriving the temperature information detected by the temperature sensor (col. 4, lines 48-59).

Regarding claim 19, Lennox et al. disclose a balloon catheter, according to claim 5, wherein a liquid agitator (syringe) connected with the liquid supply passage (132) is provided to ensure that the liquid supplied from the liquid supply passage into the balloon for filling the balloon can be reciprocated between the liquid supply passage and the inside of the balloon, so that the liquid can be agitated in the balloon (fluid, preferably saline, is injected by means of a syringe into inflation lumen 132 to inflate balloon 128 to a desired pressure, which is measured by a pressure gauge, col. 7, lines 51-55; Note: it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex Parte Masham*, 2 USPQ F.2d 1647 (1987).)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-8, 14, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox et al. (5,571,088) in view of Lennox et al. (4,955,377).

Regarding claims 1-3, 6-8, 16, and 17, Lennox et al. ('088) disclose a balloon catheter (abstract) comprising a catheter shaft (10), a balloon (22) attached to the catheter shaft, a first electrode (42) and a second electrode (44) positioned in the balloon with a clearance kept between them along the catheter shaft (Fig. 4 shows space between electrodes), high-frequency power supply leads (49) for supplying high-frequency power to the first and second electrodes (col. 4, lines 48-59; and Fig. 3), and

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a liquid supply passage (26) for supplying a liquid into the balloon (col. 4, lines 39-47) but fail to disclose wherein the surface area SA of the first electrode and the surface area SB of the second electrode are 20 mm² or more respectively; (regarding claims 2 and 7) the shortest distance E_{sd} between the first electrode and the second electrode is 1 mm or more; (regarding claims 3 and 8) a spacer for keeping the clearance between the first electrode and the second electrode is disposed between these electrodes; and (regarding claims 16 and 17) the frequency of the high-frequency power supplied to the first and second electrodes is 100 KHz to 2.45 GHz, and the high-frequency power heats the liquid supplied from the liquid supply passage into the balloon for filling the balloon, to a temperature of 50 degree Celsius to 80 degree Celsius.

However, Lennox et al. (' 377) teach annular electrical contacts 22 and 24 inside of balloon 8 have internal diameters matching the portion 10a of the catheter shaft 10 which they surround and are bonded directly to the catheter shaft. The spacing between the contacts is approximately half the length of the balloon, while the dimensions of the contacts vary according to the nature of the medical procedure to be performed. For the range of uses contemplated for this embodiment, the inner diameter of the smallest contact is about 0.050 inch, and the inner diameter of the largest contact is about 0.120 inch (col. 3, lines 29-45). In addition, Lennox et al. teach RF power supply 50 preferably operates at 650 kilohertz, but can be at any frequency within the range of about 100 kilohertz to 1 megahertz (col. 3, lines 62-68). Furthermore, Lennox et al. teach the heat from the fluid is conducted across the balloon wall into the surrounding tissue 44. For angioplasty procedures, RF power supply 50 supplies a maximum current of 1/4 amp,

and the power dissipated into fluid 36 is about 10 to 25 watts. The fluid will heat to the temperature set by the user, which may be in the range of 45 degree Celsius to 80 degree (col. 7, lines 29-42).

It would have been obvious to one having ordinary skill in the art at the time of invention to make the Lennox et al. ('088) electrodes any reasonable length as taught by Lennox et al. ('377), since one of ordinary skill in the art would clearly recognize the obvious effects of controlling the length of the electrodes.

Furthermore, Applicant's disclosure fails to provide any criticality or unexpected result associated with the specific SA for the electrodes, and the selection of any desired parameters to optimize performance is deemed to be an obvious design consideration for one of ordinary skill in the art.

Regarding claims 4 and 14, Lennox et al. disclose a balloon catheter, according to claim 1, which further comprises a temperature sensor (50) disposed inside or on the outer surface of the balloon (Fig. 3), and temperature information deriving leads for deriving the temperature information detected by the temperature sensor (col. 4, lines 48-59).

Regarding claim 18, Lennox et al. disclose a balloon catheter, according to claim 1, wherein a liquid agitator (syringe) connected with the liquid supply passage (132) is provided to ensure that the liquid supplied from the liquid supply passage into the balloon for filling the balloon can be reciprocated between the liquid supply passage and the inside of the balloon, so that the liquid can be agitated in the balloon (fluid, preferably saline, is injected by means of a syringe into inflation lumen 132 to inflate

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balloon 128 to a desired pressure, which is measured by a pressure gauge, col. 7, lines 51-55; Note: it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex Parte Masham, 2 USPQ F.2d 1647 (1987).*

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox et al. ('088) and Lennox et al. ('377) as applied to claim 1 above, and further in view of Lenker et al. (6,078,832).

Lennox et al. ('088) and Lennox et al. ('377) disclose the claimed invention except for the catheter shaft comprising an outer cylindrical shaft and an inner cylindrical shaft provided in the outer cylindrical shaft movably along the outer cylindrical shaft; the front end of the balloon is fixed to the front end of the inner cylindrical shaft while the rear end of the balloon is fixed to the front end of the outer cylindrical shaft, so that when the inner cylindrical shaft is moved relatively to the outer cylindrical shaft, the balloon can be deformed; and the liquid supply passage is formed as the clearance between the outer cylindrical shaft and the inner cylindrical shaft.

However, Lenker et al. teach an outer cylindrical shaft (50) with the proximal end of the balloon (44) attached and an inner cylindrical shaft (20) with the distal end of the balloon (44) attached (col. 8, lines 1-15; see Fig. 5). In addition, Lenker et al. teach while the inner cylindrical shaft (20) is being advanced, inflation media is provided to the

balloon (44) to inflate the balloon and center the inner cylindrical shaft (20) as it travels through the lesionous area (col. 8, lines 16-31).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to attach the balloon as taught by Lenker et al. because Lenker et al. teach the catheter can be inserted into the body lumen while entirely housed within the outer member (50) along with the balloon, which advantageously navigates through large lengths and wide ranges of curvature (col. 8, lines 16-46) and Lennox et al. ('088) and Lennox et al. ('377) teach a device that navigates through tortuous body vessels.

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox et al. in view of Lenker et al. (6,078,832).

Lennox et al. disclose the claimed invention except for the catheter shaft comprising an outer cylindrical shaft and an inner cylindrical shaft provided in the outer cylindrical shaft movably along the outer cylindrical shaft; the front end of the balloon is fixed to the front end of the inner cylindrical shaft while the rear end of the balloon is fixed to the front end of the outer cylindrical shaft, so that when the inner cylindrical shaft is moved relatively to the outer cylindrical shaft, the balloon can be deformed; the first and second electrodes are positioned with a clearance kept between them along the inner cylindrical shaft; in the case where the potential detecting electrodes are positioned outside the balloon on the front end side of the catheter shaft, the potential detecting electrodes are disposed on the inner cylindrical shaft; and in the case where the potential detecting electrodes are positioned outside the balloon on the rear end

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side of the catheter shaft, the potential detecting electrodes are disposed on the outer cylindrical shaft.

However, Lenker et al. teach an outer cylindrical shaft (50) with the proximal end of the balloon (44) attached and an inner cylindrical shaft (20) with the distal end of the balloon (44) attached (col. 8, lines 1-15; see Fig. 5). In addition, Lenker et al. teach while the inner cylindrical shaft (20) is being advanced, inflation media is provided to the balloon (44) to inflate the balloon and center the inner cylindrical shaft (20) as it travels through the lesionous area (col. 8, lines 16-31).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to attach the balloon as taught be Lenker et al. because Lenker et al. teach the catheter can be inserted into the body lumen while entirely housed within the outer member (50) along with the balloon, which advantageously navigates through large lengths and wide ranges of curvature (col. 8, lines 16-46) and Lennox et al. teach a device that navigates through tortuous body vessels.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4706688 A; US 5056532 A; US 5174290 A; US 5190540 A; US 5209749 A; US 5397308 A; US 5439446 A; US 5529574 A; US 5575772 A; US 5681308 A; US 5697965 A; US 5846199 A; US 5910129 A; US 6004269 A; US 6048333 A; US 6135997 A; US 6344028 B1; US 20020016615 A1; US 20030040742 A1; US 20040230131 A1; US 20060004286 A1; and US 20020111617 A1.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John R. Di Cicco whose telephone number is (571) 270-5039. The examiner can normally be reached on M-Th 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John R. Di Cicco/
Examiner, Art Unit 3739

/Michael Peffley/
Primary Examiner, Art Unit 3739